

# Fluanxol®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Fluanxol?

Fluanxol contains the active ingredient flupentixol decanoate. Fluanxol is used for the long-term treatment of schizophrenia, a mental illness with disturbances in thinking, emotional reactions and behaviour, and other chronic mental conditions. For more information, see Section [1. Why am I using Fluanxol?](#) in the full CMI.

### 2. What should I know before I use Fluanxol?

Do not use if you have ever had an allergic reaction to Fluanxol or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Fluanxol?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Fluanxol and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How will I be given Fluanxol?

Fluanxol is given by a doctor, nurse or other trained person. Fluanxol is given as an injection into a large muscle where it is slowly released over time.

More instructions can be found in Section [4. How will I be given Fluanxol?](#) in the full CMI.

### 5. What should I know while using Fluanxol?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Fluanxol.</li><li>• Tell your doctor if you notice any soreness of the mouth, gums, throat or other flu-like symptoms, or if you are thinking or talking about death, suicide, self-harm or harm to others.</li><li>• Keep all of your doctor's appointments so that your progress can be checked.</li><li>• If you are outdoors, wear protective clothing and use a SPF 30+ sunscreen.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li><li>• Do not take any medicines that cause drowsiness while you are using Fluanxol, unless recommended by your doctor.</li><li>• Do not stop using Fluanxol suddenly.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Fluanxol affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Be careful when drinking alcohol while you are using this medicine.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store Fluanxol below 25°C and keep it in the pack until it is time to use it.</li></ul>

For more information, see Section [5. What should I know while using Fluanxol?](#) in the full CMI.

### 6. Are there any side effects?

Some of the common side effects include movement disorders (e.g. involuntary muscle contractions, slowing of movements), restlessness, blurred vision or difficulty focusing, painful or weak muscles, tiredness, fatigue, difficulty passing urine or other urinary disorder, difficult or painful breathing, increased salivation or increased sweating, skin rash and itchy skin. Serious side effects include sudden onset of unusual movements, blood clots in the veins, serious allergic reaction, convulsions, sudden increase in body temperature, unusual stiff of the muscles and changes in consciousness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Fluanxol<sup>®</sup> (flu-ANK-sol)

Active ingredient(s): Flupentixol decanoate (flu-PEN-tic-sol deck-can-OH-ate)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Fluanxol. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Fluanxol.**

Where to find information in this leaflet:

- [1. Why am I using Fluanxol?](#)
- [2. What should I know before I use Fluanxol?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Fluanxol?](#)
- [5. What should I know while using Fluanxol?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using Fluanxol?

Fluanxol contains the active ingredient flupentixol decanoate. Fluanxol belongs to a group of medicines called thioxanthene neuroleptics. It helps to correct chemical imbalances in the brain, which may cause mental illness.

Fluanxol is used for the long-term treatment of schizophrenia, a mental illness with disturbances in thinking, emotional reactions and behaviour, and other chronic mental conditions.

Your doctor, however, may prescribe it for another purpose.

**Ask your doctor if you have any questions about why it has been prescribed for you.**

Fluanxol is not addictive.

### 2. What should I know before I use Fluanxol?

#### Warnings

**Do not use Fluanxol if:**

- you are allergic to flupentixol decanoate, to any other similar medicines (such as thioxanthenes or phenothiazines), to the ingredient fractionated coconut oil, or any of the ingredients listed at the end of this leaflet.
  - Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, or rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

- you have diminished consciousness due to any cause
- you collapse due to very low blood pressure
- you have brain damage
- you have diseases of the blood with a reduced number of red or white blood cells or platelets
- you have phaeochromocytoma, a rare tumour of the adrenal gland which sits near the kidney.

**Do not give Fluanxol to anyone who currently has alcohol poisoning, or poisoning with medicines used to produce calmness or to help you sleep, or medicines used to treat epilepsy or strong pain.**

**Do not give Fluanxol to anyone who is unconscious or in a coma.**

**Do not give Fluanxol to patients with mental illness who are highly distressed, or elderly patients who are confused and/or distressed.**

**Check with your doctor if you:**

- have allergies to any other substances such as foods, preservatives or dyes.
- have, or have had, the following medical conditions:
  - arteriosclerosis, a disease affecting the arteries
  - convulsions, fits or seizures
  - decreased blood supply to the brain
  - diabetes, a disorder of metabolism in which the amount of sugar in the blood is too high
  - glaucoma, a condition in which there is usually a build-up of pressure in the eye
  - heart and blood vessel problems
  - kidney problems
  - liver problems
  - low potassium and/or low magnesium levels in the blood
  - organic brain syndrome
  - parkinsonism, a disease of the brain affecting movement
  - risk factors for stroke
  - tardive dyskinesia, a reaction to some medicines with worm-like movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks or jaw which may progress to the arms and legs
  - treatment for cancer
  - you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots

**Also tell your doctor if you will be in a hot environment or you do a lot of vigorous exercise.**

Fluanxol may make you sweat less, causing your body to overheat.

### **Tell your doctor if you are exposed to pesticides that contain phosphorus.**

The risk of you experiencing a side effect may be increased.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

#### **Check with your doctor if you are pregnant or intend to become pregnant.**

Fluanxol may affect your fertility. If you are intending to start a family, ask your doctor for advice.

Like most medicines of this kind, Fluanxol is not recommended for use during pregnancy unless clearly necessary. The general condition of your baby might be affected by the use of this medicine.

The following symptoms may occur in newborn babies of mothers who have used Fluanxol in the last three months of their pregnancy: shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding. If your baby develops any of these symptoms you should contact your doctor.

#### **Talk to your doctor if you are breastfeeding or intend to breastfeed.**

It is not recommended that you breast-feed while using Fluanxol. Its active ingredient passes into breast milk and therefore there is a possibility that your baby might be affected.

### **Children and adolescents**

**Do not give Fluanxol to a child or adolescent.**

**There is no experience with its use in children or adolescents under 18 years old.**

## **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Fluanxol and affect how it works. These include:**

- tricyclic antidepressants, monoamine oxidase (MAO) inhibitors and lithium, medicines used to treat depression or mood swings
- phenobarbitone and carbamazepine, medicines used to treat convulsions and epilepsy
- medicines used to treat strong pain
- medicines used to produce calmness or to help you sleep
- medicines used to treat high blood pressure (hypertension), including debrisoquine, guanethidine and clonidine
- levodopa, a medicine used to treat Parkinson's disease

- medicines which stimulate the body, getting it ready for action, such as adrenaline
- metoclopramide, a medicine used to relieve nausea and vomiting
- piperazine, a medicine used to treat worm infections
- medicines used to treat changes in the rhythm or rate of the heart beat, e.g. quinidine, amiodarone, sotalol and dofetilide
- antipsychotics, a class of medicines used to treat certain mental and emotional conditions, e.g. thioridazine
- certain medicines used to treat infections, such as erythromycin, gatifloxacin and moxifloxacin
- medicines used to relieve the symptoms of allergy, including terfenadine and astemizole
- cisapride, used to treat stomach problems
- medicines that disturb water or salt balance e.g. thiazide diuretics, also called fluid or water tablets
- medicines known to increase the concentration of Fluanxol in your blood
- medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease, such as atropine or related medicines.
- medicines used to treat cancer

These medicines may be affected by Fluanxol or may affect how well it works. You may need to use different amounts of your medicines or take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Fluanxol.

## **4. How will I be given Fluanxol?**

### **How much is given**

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight and your response to the medicine.

### **Fluanxol Depot**

- Generally, the starting dose is 20 to 40 mg (1 to 2 mL). A second dose of 20 to 40 mg (1 to 2 mL) is usually given 4-10 days after the first injection, and further doses are given every 2 to 4 weeks for the majority of patients.

### **Fluanxol Concentrated Depot**

- Patients who require higher doses and/or who have problems with larger injection volumes may be given Fluanxol Concentrated Depot.

Your doctor may have prescribed a different dose.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you. Follow the instructions they give you.**

They will tell you exactly how much you will be given.

## How is Fluanxol given

- Fluanxol is given as an injection into a large muscle where it is slowly released over time. The injection should only be given by a doctor, nurse or other trained person.

## When is Fluanxol given

- It is recommended that Fluanxol is given every 2-4 weeks, depending on how your body responds to the medicine.

## How many injections will you need

- **Continue having your injections for as long as your doctor tells you to.**
- Fluanxol helps control your condition. Therefore, you will need regular injections.

## If you forget to have a Fluanxol injection

**If you forget to keep an appointment, contact your doctor as soon as you remember, so that you can make another one.**

## If you have been given too much Fluanxol (overdose)

**As Fluanxol is given to you under the supervision of your doctor, it is very unlikely that you will be given too much.**

**However, if you experience any side effects after being given Fluanxol, you should immediately:**

- phone the Poisons Information Centre in Australia (**by calling 13 11 26**) or the National Poisons Centre in New Zealand (by calling **0800 POISON** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You may need urgent medical attention.

Symptoms of an overdose may include sleepiness, coma, extreme agitation, excitement, confusion, convulsions and extremely high or low body temperature.

Uncontrollable movements may develop, and collapse due to very low blood pressure or difficulty breathing may occur. Changes in the rhythm or rate of the heart beat have been seen in Fluanxol overdose when medicines known to affect the heart have also been taken.

## 5. What should I know while using Fluanxol?

### Things you should do

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Fluanxol.**
- **Remind any doctor, dentist or pharmacist you visit that you are using Fluanxol.**
- **Tell your doctor if you notice any soreness of the mouth, gums, throat or other flu-like symptoms.**

- **Talk to your doctor or mental health professional if you are thinking or talking about death, suicide, self-harm or harm to others.**
  - These may be signs of changes or worsening in your mental illness.
- **If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.**
  - Fluanxol may affect other medicines used during surgery.
- **If you are about to have any blood tests, tell your doctor that you are taking this medicine.**
  - It may interfere with the results of some tests.
- **Keep all of your doctor's appointments so that your progress can be checked.**
  - Your doctor may do some blood and liver tests from time to time, particularly during the first months of therapy, to make sure the medicine is working and to prevent unwanted side effects.
- **Protect your skin when you are in the sun, especially between 10am and 3pm.**
- **If you are outdoors, wear protective clothing and use a SPF 30+ sunscreen.**
- **If your skin appears to be burning, tell your doctor.**
  - Fluanxol may cause your skin to be much more sensitive to sunlight than it is normally. This could cause skin rash, itching, redness, or severe sunburn.

### Call your doctor straight away if you:

- **become pregnant while using Fluanxol.**
- **notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.**
  - These are symptoms of a condition called tardive dyskinesia, which may develop in people taking similar medicines, including Fluanxol.
  - This condition is more likely to occur during long-term treatment with Fluanxol, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

### Things you should not do

- **Do not give your medicine to anyone else, even if they have the same condition as you.**
- **Do not take any medicines that cause drowsiness while you are using Fluanxol, unless recommended by your doctor.**
- **Do not miss any injections, even if you feel better.**
  - Fluanxol helps control your condition. Therefore, you will need regular injections.
- **Do not stop using Fluanxol suddenly.**

- If Fluanxol is stopped suddenly, you may experience symptoms such as nausea, vomiting, loss of appetite, diarrhoea, runny nose, sweating, aching muscles, pins and needles, sleeplessness, restlessness, anxiety, or agitation.
- Your doctor may want to gradually reduce the amount you are given before stopping completely.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Fluanxol affects you.**

It may cause drowsiness, tiredness, sleepiness or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

**Be careful when drinking alcohol while you are using this medicine.**

If you drink alcohol, drowsiness or sleepiness may be worse.

### Feeling light-headed, dizzy or faint

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

### Looking after your medicine

- **Store Fluanxol below 25°C and keep it in the pack until it is time to use it.**
  - If you take the ampoules out of the box they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date, or if the packaging is torn or shows signs of tampering. If you use it after the expiry date has passed, it may not work as well.

The expiry date refers to the last day of the month.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Fluanxol.**

It helps most people with mental illness, but it may have unwanted side effects in a few people.

If you are over 65 years of age you may have an increased chance of getting side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Musculoskeletal, connective tissue, and movement disorders:</b></p> <ul style="list-style-type: none"> <li>● restlessness</li> <li>● involuntary muscle contractions</li> <li>● slowing of movements</li> <li>● painful or weak muscles</li> </ul> <p><b>Psychiatric disorders</b></p> <ul style="list-style-type: none"> <li>● nervousness, agitation</li> <li>● depression</li> </ul> <p><b>General disorders and administration site conditions</b></p> <ul style="list-style-type: none"> <li>● headache, dizziness</li> <li>● drowsiness or somnolence</li> <li>● difficulty sleeping</li> <li>● tiredness, fatigue</li> <li>● increased sweating</li> <li>● pain at the place where your injection is given</li> </ul> <p><b>Mouth disorders</b></p> <ul style="list-style-type: none"> <li>● dry mouth</li> <li>● increased salivation</li> </ul> <p><b>Gastrointestinal disorders</b></p> <ul style="list-style-type: none"> <li>● constipation or diarrhoea</li> <li>● nausea, vomiting, dyspepsia</li> <li>● weight and appetite changes</li> </ul> <p><b>Reproductive system and breast disorders</b></p> <ul style="list-style-type: none"> <li>● impaired sexual function</li> <li>● change in your menstrual periods</li> </ul> <p><b>Renal and urinary disorders</b></p> <p>difficulty passing urine or other urinary disorder</p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Skin and subcutaneous tissue disorders</b> <ul style="list-style-type: none"> <li>• skin rash, itchy skin</li> <li>• hair loss</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<b>Musculoskeletal, connective tissue, and movement disorders:</b> <ul style="list-style-type: none"> <li>• sudden onset of unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, or shuffling walk and stiffness of the arms and legs</li> <li>• worm-like movements of the tongue or other uncontrolled movements of the mouth, tongue, cheeks or jaws, which may progress to the arms and legs</li> <li>• inability to keep still</li> </ul> <b>Psychiatric disorders</b> <ul style="list-style-type: none"> <li>• mood changes</li> </ul> <b>Eye disorders</b> <ul style="list-style-type: none"> <li>• blurred vision or difficulty focusing</li> <li>• high pressure in the eye</li> </ul> <b>General disorders and administration site conditions</b> <ul style="list-style-type: none"> <li>• fainting</li> </ul> <b>Mouth disorders</b> <ul style="list-style-type: none"> <li>• difficulty swallowing</li> <li>• swelling of the gums</li> </ul> <b>Gastrointestinal disorders</b> <ul style="list-style-type: none"> <li>• severe pain in the stomach with bloating, gut cramps and vomiting</li> </ul> <b>Cardiac disorders</b> <ul style="list-style-type: none"> <li>• irregular heart beat and changes in heart rate and blood pressure</li> </ul> <b>Reproductive system and breast disorders</b> <ul style="list-style-type: none"> <li>• breast enlargement in men</li> <li>• unusual secretion of breast milk</li> </ul> <b>Liver disorders</b> <ul style="list-style-type: none"> <li>• yellowing of the skin and/or eyes, also called jaundice</li> </ul> <b>Respiratory disorders</b> <ul style="list-style-type: none"> <li>• difficult or painful breathing</li> </ul>	<b>Speak to your doctor immediately if you notice any of these serious side effects</b>

<b>Infections and infestations</b> <ul style="list-style-type: none"> <li>• frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> </ul> <b>Blood and lymphatic system disorders</b> <ul style="list-style-type: none"> <li>• bleeding or bruising more easily than normal, nosebleeds</li> <li>• blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately</li> </ul> <b>Elderly patients with dementia</b> <ul style="list-style-type: none"> <li>• in elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics</li> </ul>	
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These may be serious side effects of Fluanxol. You may need urgent medical attention.

### Very serious side effects

Very serious side effects	What to do
<b>Immune system disorders</b> <ul style="list-style-type: none"> <li>• serious allergic reaction (symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, or hives)</li> </ul> <b>Musculoskeletal, connective tissue, and movement disorders:</b> <ul style="list-style-type: none"> <li>• convulsions</li> </ul> <b>General disorders and administration site conditions</b> <ul style="list-style-type: none"> <li>• sudden increase in body temperature, unusual stiffness of the muscles and changes in consciousness, especially in conjunction with fast heart rate and sweating. This may be due to a very rare condition called neuroleptic malignant syndrome, which has been reported with various antipsychotic medicines</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

These are very serious side effects. You may need urgent medical attention or hospitalisation.

These side effects are generally rare.

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

Ph: +61 2 8669 1000

### Distributed in New Zealand by:

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**"Fluanxol" is the registered trademark of H. Lundbeck A/S.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Fluanxol contains

<b>Active ingredient (main ingredient)</b>	<b>Fluanxol 20 mg/mL injection</b> <ul style="list-style-type: none"><li>20 mg/mL flupentixol decanoate or 40 mg/2 mL flupentixol decanoate</li></ul> <b>Fluanxol 100 mg/mL injection</b> <ul style="list-style-type: none"><li>100 mg/mL flupentixol decanoate.</li></ul>
<b>Other ingredients (inactive ingredients)</b>	fractionated coconut oil

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Fluanxol looks like

Fluanxol comes in two types of injections:

- Fluanxol Depot 20 mg/mL solution for injection - clear, colourless to slightly yellowish oil (AUST R 47109 or AUST R 47247).
- Fluanxol Concentrated Depot 100 mg/mL concentrated injection - clear, yellow to yellowish oil (AUST R 47107).

A box contains 5 ampoules.

### Who distributes Fluanxol

#### Distributed in Australia by:

Lundbeck Australia Pty Ltd  
1 Innovation Rd  
North Ryde NSW 2113